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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

DOWE, KATHERINE MARIE

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

03/11/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/656,797	Applicant(s) STARKSEN, NIEL F.	
	Examiner KATHERINE M. DOWE	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45, 47 and 49-60 is/are pending in the application.
- 4a) Of the above claim(s) 1-34, 37-45 and 51-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35, 36, 47, 49 and 50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/6/2008 and 12/2/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The following is a complete response to the amendment filed October 6, 2008.
2. Claims 1-45, 47, and 49-60 are currently pending, with claims 1-34, 37-45, and 51-60 withdrawn from consideration.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 35, 36, 47, 49, and 50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is insufficient support in the disclosure for the limitation, "the aperture having a first opening and a second opening" in lines 7-8 of claim 35. The disclosure does not recite the term "aperture" or "opening", much less a "first opening" and a "second opening", and it is unclear what equivalent structure in the specification may be defined as an aperture having a first opening and a second opening.

Additionally, there is insufficient support in the disclosure for the limitation, "when the device is in the first configuration the aperture retains a mandrel therein, the mandrel preventing release of the at least one tethered anchor, and wherein when the

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device is in the second configuration the mandrel is at least partially withdrawn from the aperture to release the at least one tethered anchor from the housing body". The Examiner notes the specification provides support merely for "the housing, balloon, and pivot mandrel may be withdrawn before or after cinching" (§0054). The specification and drawings do not disclose the mandrel may be withdrawn independently from the housing or that withdrawing the mandrel at least partially from the aperture releases at least one tethered anchor.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 35, 36, 47, 49, and 50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 35 recites: "at least one aperture disposed longitudinally [in the housing side wall] the aperture having a first opening and a second opening". It is unclear how a single aperture may comprise two openings.

Furthermore, it is unclear if the "aperture" Applicant is referring to is the lumen of the housing or the side opening of the housing. In lines 6-7 claim 35 recites, "wherein the side wall has at least one aperture disposed longitudinally therein", which suggests Applicant intends the aperture to be the opening in the side wall of the housing. However, in line 9 claim 35 recites, "when the device is in the first configuration the aperture retains a mandrel therein" and in line 12 claim 35 recites, "the mandrel is at least partially withdrawn from the aperture", which suggests Applicant intends the

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aperture to be the lumen of the housing holding the mandrel. For the purpose of Examination, the Examiner is interpreting the “aperture” to be the lumen of the housing extending in a longitudinal direction, the “first opening” of the aperture to be the longitudinal side opening of the housing, and the “second opening” of the aperture to be the distal end opening of the housing.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

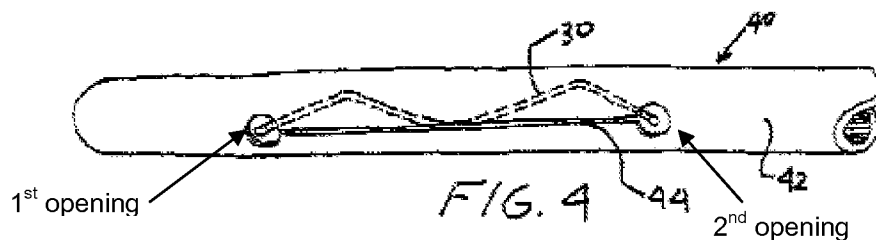
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 35, 36, 47, 49, and 50 are rejected under 35 U.S.C. 102(e) as being anticipated by Adams et al. (US 7,004,958). Adams et al. disclose a device for performing a procedure on annular tissue of a heart, the device comprising an elongate body with a housing (40) at the distal end thereof. The housing has a housing body for retaining at least one anchor (30). The Examiner notes the limitation of the tethered anchors is not positively claimed, and thus Adams et al. meets the limitation by being capable of retaining at least one tethered anchor. The housing body comprises a side wall (42) spanning a longitudinal length thereof, wherein the side wall has at least one aperture (lumen of housing body) disposed longitudinally therein. The aperture has a

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first opening along the side wall (44) and a second opening at the distal end of the housing. When the device is in a first configuration, the aperture, or lumen, retains a mandrel (50) therein, where the mandrel is capable of preventing release of the at least one tethered anchor (Fig. 7). When the device is in a second configuration, the mandrel is at least partially withdrawn from the aperture to release the at least one tethered anchor from the housing body (Fig. 8).

Alternatively, the aperture may be interpreted as the side wall aperture (44) and the first and second openings may be interpreted as shown below in annotated Figure 4:



The Examiner notes the mandrel is not positively claimed, and thus the aperture meets the claim limitations since the slit is capable of retaining a mandrel (or any other structure except a liquid) in a first configuration. In a second configuration, the aperture is capable of having the mandrel at least partially withdrawn from the aperture to release a tethered anchor.

Regarding claim 36, the elongate body comprises a rigid shaft.

Regarding claims 47 and 49, the housing body is capable of retaining an anchor comprising a curved hook (Fig. 3) and the aperture is capable of retaining a pivot

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mandrel. As previously noted, the anchors and mandrel are not positively claimed.

Thus, the structural and functional limitations of the anchors and mandrel do not hold patentable weight.

Regarding claim 50, the device further comprises at least one expandable balloon (60) that aids in driving anchors into annular tissue by urging the housing against the tissue into which the anchors will be driven.

Response to Arguments

9. Applicant's arguments filed 10/6/2008 have been fully considered but they are not persuasive.

10. Applicant argues the Examiner's interpretation of the term "aperture" is illogical and contrary to the ordinary definition of the term. The Examiner respectfully traverses the Applicant's remarks. Dictionary.com defines the term aperture as, "an opening, as in a hole, slit, crack, gap, etc.". Thus, the lumen of the device may be interpreted as an aperture in the sense that it is a "hole" or "gap" in the housing, wherein the lumen or aperture is bounded by the housing walls, not some "imaginary volume of space" as Applicant contends. Furthermore, the Examiner notes the specification does not use the term "aperture" at all and the disclosure is unclear as to what aperture Applicant is referring to, especially with the claim amendments that the aperture comprises first and second openings and retains the mandrel therein.

11. Furthermore, Applicant argues the aperture of Adams is merely a breakaway slot in the side wall of the housing and while the side wall has an aperture therethrough, it

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does not have an aperture disposed longitudinally therein. The Examiner respectfully traverses Applicant's remarks. The aperture 44 of Adams clearly extends in the longitudinal direction of the side wall and as acknowledged by Applicant, the side wall has an aperture therethrough. Thus, it is clear aperture 44 is disposed such that the side wall has an aperture longitudinally therein. However, in an alternate interpretation of Adams as shown above, the aperture may be interpreted as the lumen of the housing (40), which clearly extends in the longitudinal direction of the side wall such that the side wall has an aperture disposed longitudinally therein.

12. Finally, Applicant argues Adams does not disclose a mandrel preventing release of the at least one tethered anchor. The Examiner first notes the limitation presents the issue of new matter as shown above. Secondly, the mandrel is not positively claimed and thus as the claim is written, the aperture need only be capable of retaining a mandrel that prevents the release of a tethered anchor. However, the Examiner notes the mandrel of Adams is indeed capable of preventing the release of an anchor by positioning the anchor such that it is not adjacent the slot (42) of the housing. Whereas, when the mandrel is moved, the mandrel causes the anchors to pivot out of the housing (Fig. 8). The configuration of the slot and the position of the mandrel work together to prevent the anchors from being released from the housing.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

14. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE M. DOWE whose telephone number is (571)272-3201. The examiner can normally be reached on M-F 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kevin T. Truong/
Primary Examiner, Art Unit 3734

Katherine Dowe
March 9, 2009

/K. M. D./
Examiner, Art Unit 3734